# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 Lyophilisate and solvent for suspension for injection for cattle

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 4 ml contains:
Bovine Parainfluenza 3 virus (Pi3V), modified live strain RLB 103 $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$
Bovine Respiratory Syncytial Virus (BRSV), modified live strain 375 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$

## 3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

## 4. PACKAGE SIZE

5 doses
25 doses

## 5. TARGET SPECIES

Cattle

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD (S)

Withdrawal period(s): Zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP:
Once reconstituted use immediately

## 11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze. Protect from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4212

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL ON GLASS VIAL – LYOPHILISATE (5 and 25 doses)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 Lyophilisate for cattle

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pi3V, BRSV

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses
25 doses

## 4. ROUTE(S) OF ADMINISTRATION

IM

## 5. WITHDRAWAL PERIOD

Withdrawal period(s): Zero days.

## 6. BATCH NUMBER

Lot {number}

## 7. EXPIRY DATE

EXP:
Once reconstituted use immediately.

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL ON GLASS VIAL – SOLVENT (20 ml and 100 ml)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 solvent for cattle

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses (20 ml)
25 doses (100 ml)

## 4. ROUTE(S) OF ADMINISTRATION

IM

## 5. WITHDRAWAL PERIOD (S)

Withdrawal period(s): Zero days.

## 6. BATCH NUMBER

Lot {number}

## 7. EXPIRY DATE

EXP:
Once reconstituted use immediately.

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# Rispoval 2 / BRSV + Pi3 Lyophilisate and solvent for suspension for injection for cattle

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 Lyophilisate and solvent for suspension for injection for cattle.

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 4 ml contains:

**Active substances:**
*Lyophilisate*

| | |
|---|---|
| Bovine Parainfluenza 3 virus (Pi3V), modified live strain RLB 103 | $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$ |
| Bovine Respiratory Syncytial Virus (BRSV), modified live strain 375 | $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$ |

$CCID_{50}$ = Cell Culture Infectious Dose 50%

**Adjuvant**

| | |
|---|---|
| Aluminium hydroxide gel | 0.8 ml (equivalent to 24.36 mg of aluminium hydroxide) |

Lyophilisate: Slightly whitish to yellowish freeze-dried pellet.
Solvent: Pinkish to orange-brown turbid liquid, which might contain loose sediment. On shaking well, the sediment is easily resuspended.

## 4. INDICATION(S)

Active immunisation of cattle from 12 weeks of age to:

- reduce virus excretion caused by bovine Pi3 virus and
- reduce virus excretion caused by BRSV infection.

Onset of immunity: 3 weeks after the basic vaccination scheme.

Duration of immunity: 6 months after the basic vaccination scheme for BRSV. Duration of immunity has not been established for bovine Pi3 virus.

## 5. CONTRAINDICATIONS

None.

## 6. ADVERSE REACTIONS

Transient and mild hyperthermia which can last for 2 days and a transient, minor local inflammation reaction of up to 0.5 cm which disappears within 15 days can occur very commonly after administration of the vaccine. Very rarely, the vaccine may cause hypersensitivity reactions. In case of anaphylactic reaction, symptomatic treatment should be provided.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even though those not already listed in this package leaflet or you think the medicine has not worked, please inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

## 7. TARGET SPECIES

Cattle.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

**Dose:** 4 ml

**Route:** Intramuscular use

**Vaccination scheme:**
*Basic vaccination:* Two doses of Rispoval 2, 3-4 weeks apart from 12 weeks of age.
*Re-vaccination:* If continued protection against BRSV is required, then animals should be revaccinated after 6 months. The duration of immunity of the Pi3 component is not known.
Animals should be preferably vaccinated at least 3 weeks before a period of stress or high infection risk such as re-grouping or transport of animals, or the start of autumn season.

## 9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute the vaccine by adding the solvent to the vial containing the lyophilisate.

When the lyophilisate and solvent are filled in equally sized vials, inject the entire solvent into the vial containing the lyophilisate.

When the lyophilisate is filled in a smaller vial size than the solvent, the reconstitution of the vaccine is carried out in 2 steps:

1. Inject 10ml of the solvent on the lyophilised plug in the vial containing the lyophilisate.
2. Shake well and extract the reconstituted lyophilised fraction from the vial and mix with the remaining solvent in the liquid fraction vial.

Shake well before use.

Reconstituted product: pink-orange turbid suspension with loose sediment.

## 10. WITHDRAWAL PERIOD (S)

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C). Do not freeze. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf-life after reconstitution according to directions: use immediately

## 12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety and efficacy of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
Reactions after administration of an overdose of vaccine are not different from those after the single dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent recommended for use with the veterinary medicinal product.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

## 15. OTHER INFORMATION

- Type I glass vial containing 5 or 25 doses (20 or 100 ml) of solvent, closed with chlorobutyl rubber stopper and sealed with aluminium cap.

– Type I glass vial containing 5 or 25 doses of lyophilisate, closed with bromobutyl rubber stopper and sealed with aluminium cap.

Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of solvent (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of solvent (100 ml).

Not all pack sizes may be marketed.

For animal treatment only.
To be supplied only on veterinary prescription.

Approved 02 February 2021